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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/788,413	03/01/2004	David M. Anderson	05900010AA	4972	
30743 Whitham C	7590 06/11/200°	EXAMINER			
WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C. 11491 SUNSET HILLS ROAD			WANG, SHENGJUN		
SUITE 340 RESTON, VA 20190		ART UNIT	PAPER NUMBER		
1.201011, 111	125151, 11126176			1617	
			MAIL DATE	DELIVERY MODE	
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			06/11/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)		
	10/788,413	ANDERSON ET AL.		
Office Action Summary	Examiner	Art Unit		
	Shengjun Wang	1617		
The MAILING DATE of this communication app	pears on the cover sheet with	the correspondence address		
Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	PATE OF THIS COMMUNICA 136(a). In no event, however, may a repl will apply and will expire SIX (6) MONTH e, cause the application to become ABAN	ATION.  ly be timely filed  IS from the mailing date of this communication.  NDONED (35 U.S.C. § 133)		
Status		•		
1) Responsive to communication(s) filed on				
	s action is non-final.			
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under be	Ex parte Quayle, 1935 C.D. 1	11, 453 O.G. 213.		
Disposition of Claims				
4)⊠ Claim(s) <u>1-105</u> is/are pending in the applicatio	on.			
4a) Of the above claim(s) is/are withdra				
5) Claim(s) is/are allowed.				
6) Claim(s) is/are rejected.				
7) Claim(s) is/are objected to.				
8) Claim(s) <u>1-105</u> are subject to restriction and/o	r election requirement.			
Application Papers		· ·		
9) The specification is objected to by the Examine	or.			
10) The drawing(s) filed on is/are: a)		the Examiner		
Applicant may not request that any objection to the	•			
Replacement drawing sheet(s) including the correc				
11) The oath or declaration is objected to by the Ex				
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 1	19(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:				
1. Certified copies of the priority document	ts have been received.			
2. Certified copies of the priority document	ts have been received in App	olication No		
3. Copies of the certified copies of the prio	rity documents have been re	ceived in this National Stage		
application from the International Burea	. , , ,			
* See the attached detailed Office action for a list	of the certified copies not re	ceived.		
Attachment(s)				
1) Notice of References Cited (PTO-892)		nmary (PTO-413)		
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)		Mail Date rmal Patent Application		
Paper No(s)/Mail Date	6) 🔲 Other:			

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## **DETAILED ACTION**

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-22, 75-81, 83-91, 93, 95, 98, 100-105 drawn to a liquid composition comprising dantrolene, classified in class 424, subclass 400.
  - II. Claims 23-29, 94, 96-97, 99 drawn to particulates composition of dantrolene, classified in class 424, subclass 489.
  - III. Claims 30-74 and 82, 92 drawn to a method of treating a diseases associated with ryanodine receptor, classified in class 424, subclass 400; class 514, subclass 389.
- 2. Inventions groups (I and II) and group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product as claimed can be practiced with another materially different product, such as aminodantrolene.
- 3. Inventions group I and group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation. Particularly, the inventions are directed to different physical forms recognized in the art as distinct each from the other, evidenced by the different class/subclass.

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4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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- 5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 6. Claims 1-105 are generic to the following disclosed patentably distinct species: A) various medicament; and (if group III is elected) B) diseases or conditions been treated. The species are independent or distinct because of the distinct chemical and physiological properties of those medicaments and for the different symptoms and etiologies of those diseases or conditions. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Note in electing a medicament, applicants are require to identify the active ingredient(s) of single disclosed medicament. See, claims 4, 26-29, 37 of some of the active ingredients, and claim 36 for some of the diseases and conditions. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

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process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shengjun Wang Examing Primary Examiner Art Unit 1617